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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,862	01/15/2004	Douglas H. Irish	DKP 0101 PUS1	4622

22045 7590 08/25/2006

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EXAMINER

AHMED, AAMER S

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/757,862	Applicant(s) IRISH, DOUGLAS H.	
	Examiner Aamer S. Afimed	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-15,17-20 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-15,17-20 and 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 3-15, and 17-20 rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing, Jr. (US 5,688,248) in view of Miller et al (US 5,671,983).

Lessing discloses a device comprising a pouch (15) having an interior formed by connected front and back sides, the front side of the pouch having an exposable opening (21), the back side of the pouch (24) having an exposable opening; a fill drain tube or catheter sleeve (25) connected to the exposable opening of the front side of the pouch and extending into the interior of the pouch, string attachment means (18), a catheter clamp (26) connected to one of the front and back sides of the pouch within the interior of the pouch.

Lessing Jr. fails to disclose that the device includes an internally disposed hand covering element in communication with the exterior of the pouch, or peel away seals, adhesive on the back of the pouch.

Miller discloses a similar device with an internally disposed mittens covering element in communication with the exterior of the pouch (see fig. 5) and peel away seals (638) on the back of the pouch.

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing Jr. by adding the mittens, and peel away seals of the type taught by Miller et al, in order to provide a sterile environment.

Furthermore as to claims 13, 17 and 19, it would have been an obvious matter of design choice to include plastic on the pouch as this is a common material used in for catheter and color the pouch, drain tube, catheter sleeve and the hand covering element a different color as the applicant has not disclosed that altering the color solves any stated problem and it appears that the invention would work equally well if the parts were the same color.

Claims 22-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lessing, Jr. (US 5,688,248) in view of Miller et al (US 5,671,983) and further in view of Militzer (US 5,496,282)

As to claim 22, Lessing and Miller disclose the device as described above, but fail to disclose that the fill-drain tube is connected at a first end by a Y connection.

Militzer et al discloses a similar device with a Y-connector (see fig. 1).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the device of Lessing in view of Miller by adding the Y-connector of the type taught by Militzer et al in order to connect to both a fill source and drain receptacle.

As to claims 23-30, Lessing Jr. and Miller disclose the method using the device as described above, but fail to disclose the step of clamping the catheter with the catheter clamp prior to connecting the fill-drain tube and removing the clamp after connecting to the fill drain tube.

Militzer et al discloses a similar device and method including the step of clamping the catheter with the catheter clamp prior to connecting the fill-drain tube and removing the clamp after connecting to the fill drain tube (col. 5 line 5).

It would have been obvious to one having ordinary skill in the art at the time of invention by applicant to modify the method of Lessing Jr. in view of Miller et al by adding the step of clamping the tube as taught by Militzer et al, in order to maintain sterility of the device components.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aamer S. Ahmed whose telephone number is 571-272-5965. The examiner can normally be reached on Monday thru Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Aamer S. Ahmed', with a stylized flourish at the end.

A. Ahmed

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NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700